

REMARKS

Summary of the Office Action

Claims 1-23 are pending in the application. Claims 3, 4, 9, 10, 13, 14, 19, and 20 have been withdrawn from consideration.

Claims 1, 2, 5-8, 11, 12, and 23 have been rejected under 35 USC 102(b) as allegedly anticipated by U. S. Patent No. 5,843,172 to Yan ("Yan").

Claims 15-17 have been rejected under 35 USC 103(a) as allegedly obvious over International Publication No. 96/26682 to Globerman et al. ("Globerman") in view of U. S. Patent No. 6,071,305 to Brown et al. ("Brown").

Claim 21 has been rejected under 35 USC 103(a) as allegedly obvious over *Globerman* in view of U. S. Patent No. 5,882,335 to Leone et al. ("Leone").

Claim 22 has been rejected under 35 USC 103(a) as allegedly obvious over *Globerman* in view of obvious matters of design choice.

Claim 15 and 18 have been rejected under 35 USC 103(a) as allegedly obvious over European Patent No. EP 1057460 to Tower et al. ("Tower") in view of *Globerman* and *Brown*.

Applicant's Response

Applicant has amended independent claims 1, and 23 to recite that "the tubular member [has] one or more hollow core sections" and "pores providing fluid communication between the one or more hollow core sections and the external environment." Support for this recitation is found in the specification, e.g., in the figures.

As amended, independent claims 1 and 23 are not anticipated by Yan. A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1087). Further, an anticipating prior art patent or printed publication must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

Yan does not disclose, either expressly or inherently, each and every element set forth in amended claims 1 and 23. For example, amended claims 1 and 23 require at least the following features:

- (1) one or more hollow core sections,
- (2) pores providing fluid communication between the one or more hollow core sections and the external environment,
- (3) a bioabsorbable polymer contained in the one or more hollow core sections.

Yan discloses an implantable prosthesis having porous cavities and a construction allowing drugs to be loaded directly into the porous cavities without substantially weakening the structural and mechanical characteristics of the prosthesis. In particular, the porous cavities in Yan are formed by agglomerating metal particles through a sintering process, or by having a core of the prosthesis formed by a first sintered layer of dense particles surrounded by a sintered second layer of less dense particles, or by having a solid core surrounded by

a layer of sintered particles. *Yan*, Summary of the Invention. The dimensions of the porous cavities are a function of particle size and dimension, and these porous cavities are impregnated with a medication by immersing the prosthesis in that medication. *Yan*, Col. 4, line 54; Col. 5, lines 39-41.

The Examiner has characterized FIG. 2 of *Yan* as representing "a stent **20** formed of a tubular member with a lumen therein and a multiplicity of pores **18** in fluid communication with the lumen." This is incorrect. FIG. 2 of *Yan* illustrates a partial microscopic view of a sintered wire that has several porous cavities **18**. *Yan* does not disclose or suggest that the wire has one or more hollow core sections with pores providing fluid communication between the hollow core sections and the external environment, but instead teaches a wire having a **denser core** surrounded by a particled layer of lesser density. Additionally, *Yan* does not disclose or suggest having a bioabsorbable polymer contained in the hollow core and eluted into a vessel through the pores, but instead teaches impregnating the pores with a medication by immersing the prosthesis in the medication, which causes the large amount of medication to be contained in the surface pores.

For at least these reasons, *Yan* cannot anticipate independent claims 1 and 23 or the claims that depend thereon.

With regard to the 35 USC 103(a) rejections, independent claim 15, as amended, is not obvious over *Globerman* in view of *Brown*. To determine whether a rejection under section 103 is proper, it is necessary to determine the subject matter of the claimed "as a whole," and consider all the subject matter defined in the claim under consideration, not most or part of it. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 228 USPQ (BNA) 90 (Fed. Cir. 1985).

The combination of *Globerman* and *Brown* does not provide each and every element set forth in amended claim 15 when the subject matter of claim 15 is considered "as a whole." For example, amended claim 15 requires at least that the therapeutic agent be dispersed "with a composition that controls elution of the therapeutic agent by biodegrading over a predetermined period of time." *Globerman* does not teach or suggest that the delivery of the therapy agent may be controlled by biodegradation of a bioabsorbable polymer. Instead, *Globerman* states only that "the lumen of the tubular material may contain radiopaque material or pharmacological substance" and that "[t]he wall of the tubing may have one or more small or miniature openings so that such pharmacological substances can be dispersed."

The Examiner has cited *Brown* to cure the deficiencies in *Globerman*, stating that "Brown teaches that bioabsorbable polymers (col. 8, lines 62-65; col. 9, line 1) are used as means for controlling release into the lumen of the patient."

In the passage cited by the Examiner, *Brown* only discloses that a biocompatible delivery matrix may be lodged in cavities disposed on a stent, and that the matrix may be biodegradable or non-biodegradable. In the following paragraphs, *Brown* further discloses that delivery of the matrix may be controlled by use of a membrane, or by the size and number of the cavity inlets, or by an osmotic agent that periodically expands and expels matrix from the cavities. *Brown*, Col. 9, lines 15-17, 30-32; Col. 10, lines 22-24. Therefore, the Examiner's citation can hardly be read to include with "a composition that controls elution of the therapeutic agent by biodegrading over a predetermined period of time," as claimed by Applicant.

The deficiencies in *Globerman* and *Brown* also are not resolved by *Tower* and *Leone*, because *Tower* provides no teachings relevant to drug-eluting stents, and because *Leone* was cited by the Examiner only as relevant to certain aspects of dependent claim 21.

For the foregoing reasons, the withdrawal of the rejections of independent claims 1, 15, and 23 is respectfully requested. The withdrawal of the rejections of all the dependent claims is also respectfully requested, for at least the same reasons as independent claims 1, 15, and 23.

In addition, because claims 1 and 15 are generic to all of the disclosed embodiments, withdrawn claims 3, 4, 9, 10, 13, 14, 19 and 20 should be rejoined in this case.

Conclusion

In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance. An early and favorable action is earnestly requested.

Dated: October 5, 2006 Respectfully submitted,



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